

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N-0426]

Display Date	3-15-06
Publication Date	3-16-06
Certifier	L. CLAWSON
	DDM

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Notice of Participation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Notice of Participation—(OMB Control Number 0910-0191)—Extension**

Section 12.45 (21 CFR 12.45), issued under section 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371), sets forth the format and procedures for any interested person to file a petition to participate in a formal evidentiary hearing, either personally or through a representative. Section 12.45 requires that any person filing a notice of participation state their specific interest in the proceedings, including the specific issues of fact about which the person desires to be heard. This section also requires that the notice include a statement that the person will present testimony at the hearing and will comply with specific requirements in § 12.85, or, in the case of a hearing before a Public Board of Inquiry (21 CFR 13.25). In accordance with § 12.45(e) the presiding officer may omit a participant's appearance.

The presiding officer and other participants will use the collected information in a hearing to identify specific interests to be presented. This preliminary information serves to expedite the pre-hearing conference and commits participation.

The respondents are individuals or households, State or local governments, not for profit institutions, and businesses, or other for profit groups and institutions.

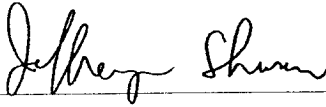
In the **Federal Register** of November 1, 2005 (70 FR 65904), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received. However, it was not related to the information collection.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.45	264	1	264	3	792

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: **MAR 10 2006**  
March 10, 2006.



Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 06-????? Filed ??-??-06; 8:45 am]

BILLING CODE 4160-01-S

